GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:4231
ANSWERED ON:21.08.2000
LICENCES FOR PRODUCTION OF MEDICINE/DRUGS
JAI BHADRA SINGH

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the terms and conditions laid down for grant of manufacturing licence for production of finished medicines and bulk drugs;

(b) whether any inspection is made before issuance or renewal of such licences;

(c) if so, the details thereof along with the validity period of these licences;

(d) whether renewal of these licences takes many years for the purpose; and

(e) if so, the reasons therefore and the corrective measures taken in this direction?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (PROF. RITA VERMA)

(a) Production of finished medicines and bulk drugs are granted by the State Licensing Authorities under the Drugs and Cosmetics Rules, 1945 after ensuring that the manufacturer will comply with the terms and conditions regarding premises, equipment, storage and manufacture under the supervision of competent technical staff and compliance with Good Manufacturing practices.

(b) & (c) Under the said rules, licences for manufacture are granted after the inspection of the manufacturing premises by the concerned Drug Inspector. The Inspector examines the entire premises, Plant and appliances as well as the process of manufacture and submits a detailed report of the Licensing Authority for consideration. These licences are granted or renewed by the State Licensing Authorities for a maximum period of two years.

(d) & (e) No fixed time limit is laid down under the Drugs & Cosmetics Rules 1945 for renewal of licences.Sometimes delays take place in renewal. There appears to be a need to streamline by extending the duration of validity of licences.